the agency now posts this information on the Internet on FDA's home page at *http://www.fda.gov*. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from July 1, 2008, through September 30, 2008. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JULY 1, 2008, THROUGH SEPTEMBER 30, 2008.

PMA No. Docket No.	Applicant	TRADE NAME	Approval Date
P060037 FDA–2008–M–0522	Zimmer, Inc.	NEXGEN LPS–FLEX MOBILE & LPS MOBILE BEARING KNEE SYSTEM	December 10, 2007
P850048 (S021) FDA–2008–M–0425	Beckman Coulter, Inc.	ACCESS HYBRITECH PSA REAGENTS	May 9, 2008
P060027 FDA–2008–M–0426	ELA Medical, Inc.	OVATIO CRT–D SYSTEM	May 15, 2008
P060039 FDA–2008–M–0478	Medtronic Cardiac Rhythm Disease Management	ATTAIN STARFIX MODEL 4195 LEAD	June 13, 2008
P070013 FDA–2008–M–0402	Colbar Lifescience Ltd.	EVOLENCE COLLAGEN FILLER	June 27, 2008
P050040 FDA–2008–M–0437	Invitrogen Corporation	SPOT–LIGHT HER2 CISH KIT	July 1, 2008
P070006 FDA–2008–M–0477	Oxford Immunotec, Ltd.	T SPOT–TB TEST	July 30, 2008
P040037 (S007) FDA–2008–M–0467	W.L. Gore & Associates, Inc.	VIABAHN ENDOPROSTHESIS	August 14, 2008
P050028 FDA–2008–M–0501	Roche Molecular Systems, Inc.	COBAS TAQMAN HBV TEST	September 4, 2008
P060022 FDA–2008–M–0515	Bausch & Lomb, Inc.	AKREOS POSTERIOR CHAMBER INTRAOCULAR LENS	September 5, 2008

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html*.

Dated: January 15, 2009.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E9–2685 Filed 2–9–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Science Board to the Food and Drug Administration; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Science Board to the Food and Drug Administration (Science Board).

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on Tuesday, February 24, 2009, from 8 a.m. to 3 p.m.

Addresses: Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Carlos Peña, Office of the Commissioner, Food and Drug Administration (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6687, or

FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512603. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The Science Board will hear about and discuss updates from the agency on the continued assessment of Bisphenol A (BPA) in FDA-regulated products. The Science Board will hear about the plans for the following: (1) The review of FDA Center's science programs, (2) the review of each Center's projects within scientific priority areas, and (3) the handling of biospecimens used for genomic and proteomic analyses. The Science Board will also hear updates from two working groups on economically motivated adulteration of FDA-regulated products and rapid detection of Salmonella in foods.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 17, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 11, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 12, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Dr. Carlos Peña at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 30, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–2797 Filed 2–9–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 18, 2009, from 8:30 a.m. to approximately 5:30 p.m. and on February 19, 2009, from 8:30 a.m. to approximately 4 p.m.

Location: Hilton Washington DC/Silver Spring, 8727 Colesville Rd., Silver Spring, MD 20910.

Contact Person: Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On February 18, 2009, in the morning, the committee will discuss and make recommendations on the selection of strains to be included in the influenza virus vaccine for the 2009—2010 influenza season and in the afternoon will discuss the utility of adding a second B strain to current seasonal influenza vaccines. On February 19, 2009, the committee will discuss the conducting of clinical studies of pandemic influenza vaccine in the pediatric population in the absence of an influenza pandemic.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2009 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 12, 2009. Oral presentations from the public will be scheduled between approximately 1:15 p.m. and 1:45 p.m. on February 18, 2009, and between approximately 1:30 p.m. and 2 p.m. on February 19, 2009. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or